UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/367,361 | 08/11/1999 | BURKHARD SCHLUTERMANN | 4-21233/A | 4260 |

1095 7590 05/16/2003

THOMAS HOXIE
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

| EXAMINER | |
|---|---|
| SPEAR, JAMES M | |
| **ART UNIT** | **PAPER NUMBER** |
| 1615 | 17 |

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action

| Application No. | Applicant(s) |
|---|---|
| 09/367,361 | SCHLUTERMANN, B |
| **Examiner** | **Art Unit** |
| JAMES M. SPEAR | 1615 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

THE REPLY FILED *May 1, 2003* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *THREE* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *May 5, 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see NOTE below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
*SEE ATTACHMENT In response to applicant's Response After Final Rejection, filed May 01, 2003.*

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: _____

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

10. ☐ Other:

James M. Spear

**JAMES M. SPEAR**
**PRIMARY EXAMINER**
**ART UNIT 1615**

ATTACHMENT TO ADVISORY ACTION

Applicants feel their smaller particle sizes for the active ingredient, oxcarbazepine and single hydrophilic coating distinguish the claimed invention over the Bourquin reference, US 5,472,714. While Bourqin only mentions coarse granules having a particle size of 2 to 6 mm, the actual drug particles would be smaller because the granules contain excipients. As has been previously stated, (Paper No. 10), it is generally accepted in the art that drugs should be in a finely ground state to be immediately available to the system for absorption at the point of desired delivery. It would be reasonable to expect one skilled in the art would use finely ground particles in such dosage forms. While the art may be silent on the actual size of the pure drug alone it is known in the art that drug granulations having particle sizes of 2 to 6 mm may comprise particulate pure drug particles of much more finite particle size. Applicant's examples show the same proces of granulation in formulating their tablets as Bourquin. While Bourquin uses a double layer tablet coating as opposed to applicant's single layer, the components are identical and therefore not a patentable distinction. Both processes being the

same the products would be the same. The final tablet product of applicant is not considered patentably distinct from the Bourquin tablets.

James M. Spear

JAMES M. SPEAR
PRIMARY EXAMINER
ART UNIT 1615
05-14-2003